



MedImmune

FluMist[®] Update

Influenza Vaccine Summit Meeting

Atlanta, GA

April 19, 2007

Refrigerated FluMist[®] Launch for 2007-08

	FluMist (Frozen Formulation) Seasonal Vaccine No Longer Manufactured*	FluMist (Refrigerated Formulation) 2007/2008 Launch
Regulatory Status & Age Indication	Licensed in U.S. in 2003 Healthy persons aged 5 – 49 years	Licensed in U.S. in 2007 Healthy persons aged 5 – 49 years
Storage	-15° C Freezer	2-8° C Refrigerator
Excipients	SPG	SPG, arginine, hydrolyzed porcine gelatin
Preservatives	None	None
Dose Volume	0.5mL (0.25mL per nostril)	0.2mL (0.1mL per nostril)

*Frozen formulation may be used for pandemic vaccine.

Refrigerated FluMist[®]

- **Launch planned for 2007-08 season**

User stores vaccine refrigerated (2 - 8°C)

Current indication – healthy persons aged 5-49 years

Expanded indication for children aged 12-59 months without history of wheeze/asthma

- Under FDA review

- May 28 PDUFA date

Plan to manufacture 7 M doses

- **Pricing and Distribution**

Commercial – \$17.95 per dose¹

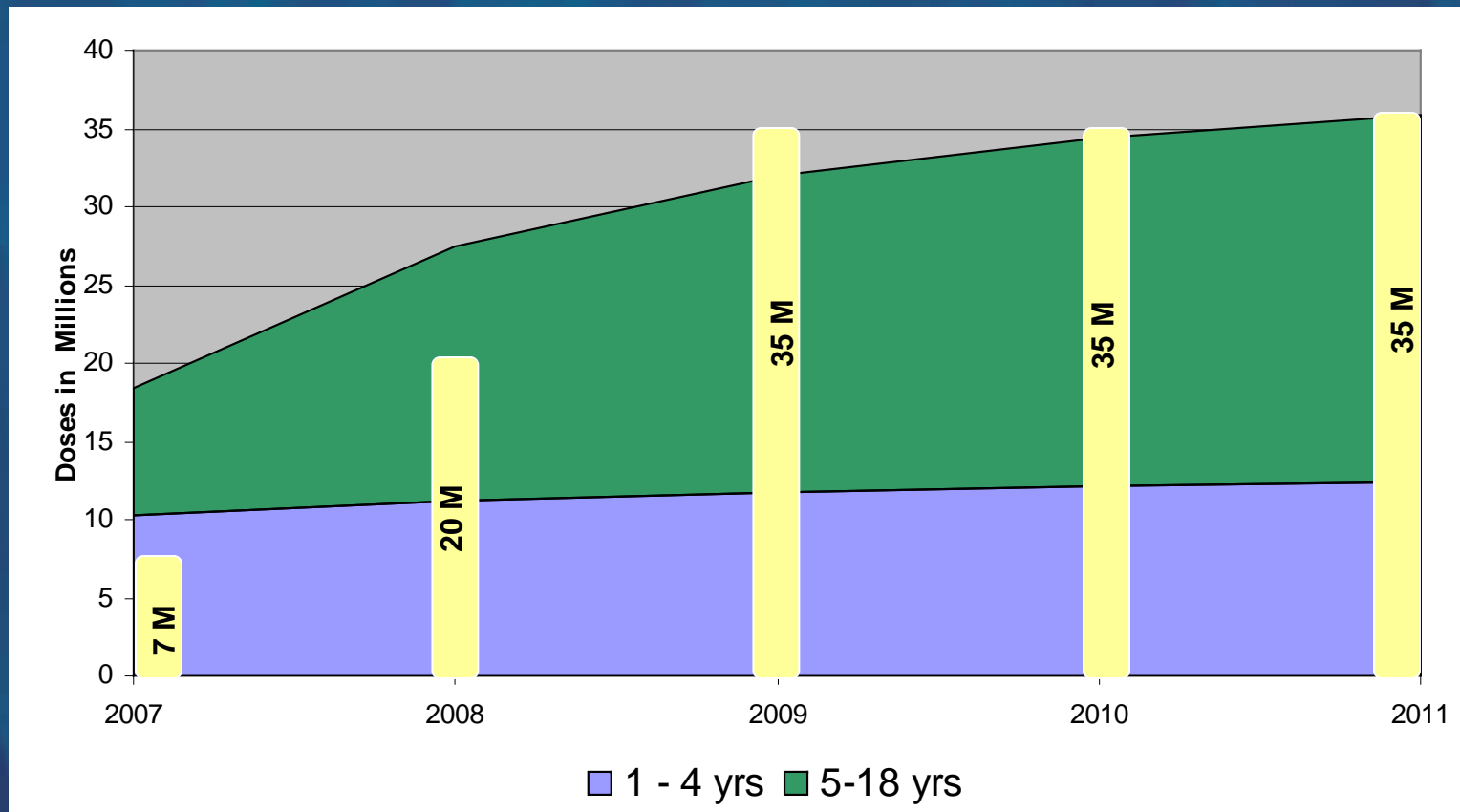
(AmerisourceBergen/McKesson)

VFC contract – \$16.90 per dose¹ (project depots)

- **Availability targeted to begin in August**

¹ Excludes Federal Excise Tax

Impact of Expanded Recommendations *School-Aged Children*



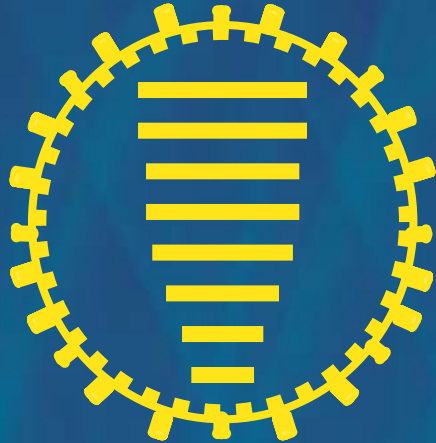
FluMist® Capacity

Update on Production of Vaccine *Plasmid Rescue*

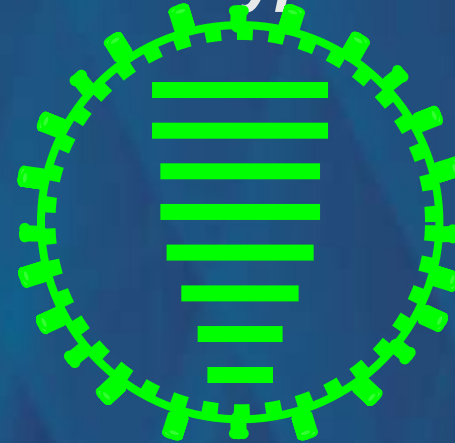
- Approved by FDA in 2006
- Alternate method for production of seasonal vaccine strains
- Required method for production of HPAI pandemic strains

Classical Reassortment

Master Donor Virus



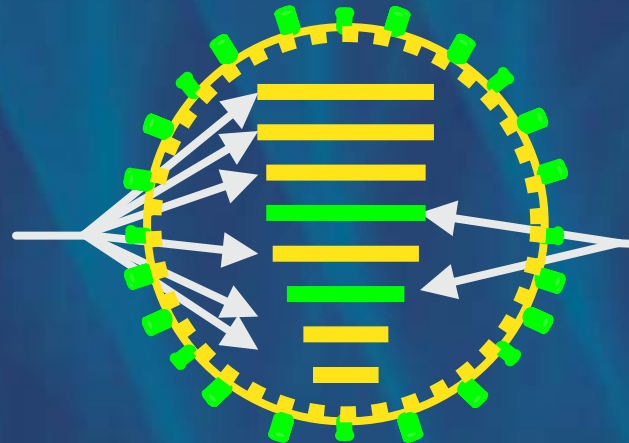
New Wild Type Strain



Co-infect cells

256 possible combinations

Six genes from MDV for *ca,ts,att*



Hemagglutinin and neuraminidase genes from wild type for immunity

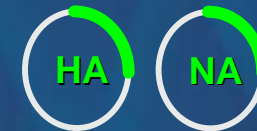
6:2 Vaccine Seed Strain

Plasmid Rescue

*Master Donor
Virus Plasmids*



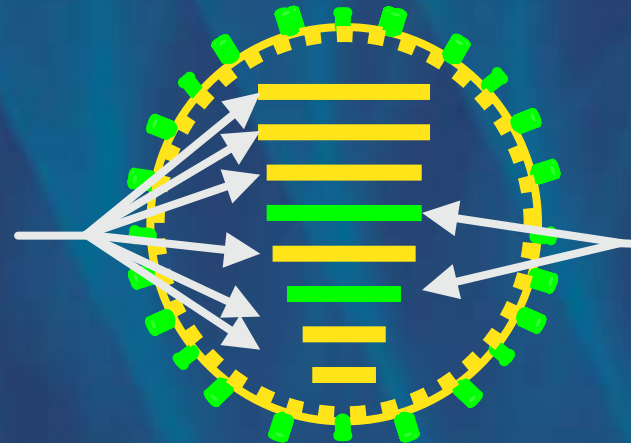
*New Wild Type
Strain Plasmids*



Electroporate Vero cells

Only one possible combination

Six genes from
MDV for
ca,ts,att



Hemagglutinin and
neuraminidase genes
from wild type for
immunity

6:2 Vaccine Seed Strain

Advantages of Plasmid Rescue

- **No genetic modifications introduced**
 - Same vaccine seeds as classical reassortment method
 - RNA sequence equivalent to classical reassortant
- **Further advantages**
 - Removes risk of exposure to adventitious agents in the wild type isolate
 - Fewer random mutations observed
 - Identical bulk production process
- **Timing of plasmid rescue is predictable**
 - Manufacturing can begin earlier, extending campaign
 - Earlier release of vaccine to the end user
 - Allows for greatest number of vaccine doses delivered



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